Complete Summary

GUIDELINE TITLE

Antithrombotic therapy during percutaneous coronary intervention: the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy.

BIBLIOGRAPHIC SOURCE(S)

Popma JJ, Berger P, Ohman EM, Harrington RA, Grines C, Weitz JI. Antithrombotic therapy during percutaneous coronary intervention: the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. Chest 2004 Sep;126(3 Suppl):576S-99S. [143 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Popma JJ, Ohman EM, Weitz J, Lincoff AM, Harrington RA, Berger P. Antithrombotic therapy in patients undergoing percutaneous coronary intervention. Chest 2001 Jan;119(1 Suppl):321S-336S.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s)/intervention(s) for which important revised regulatory and/or warning information has been released.

- February 28, 2008, Heparin Sodium Injection: The U.S. Food and Drug Administration (FDA) informed the public that Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection and their heparin lock flush solutions. Alternate heparin manufacturers are expected to be able to increase heparin production sufficiently to supply the U.S. market. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension.
- June 8, 2007, Troponin-I Immunoassay: Class I Recall of all lots of the Architect Stat Troponin-I Immunoassay. The assay may report falsely elevated or falsely decreased results at and near a low level, which may impact patient treatment.

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SCOPE

DISEASE/CONDITION(S)

Conditions, such as ischemic heart disease, requiring percutaneous coronary intervention

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Cardiology
Critical Care
Emergency Medicine
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide evidence-based recommendations for the use of antithrombotic therapy in the percutaneous coronary intervention (PCI) setting

TARGET POPULATION

Patients undergoing percutaneous coronary intervention (PCI), including all forms of percutaneous mechanical revascularization, which may involve the use of a single device or multiple new devices and balloons

INTERVENTIONS AND PRACTICES CONSIDERED

Management/Treatment with Antithrombotic Therapy

1. Oral antiplatelet agents
   - Aspirin therapy
   - Clopidogrel
   - Ticlopidine
   - Aspirin therapy in combination with clopidogrel or ticlopidine

   Note: Dipyridamole is considered but not recommended as an alternative in aspirin-sensitive patients undergoing percutaneous coronary intervention (PCI). Cilostazol is considered but not recommended as an alternative oral antiplatelet agent.

2. Platelet glycoprotein (GP) IIb/IIIa antagonists
   - Abciximab
   - Eptifibatide
   - Tirofiban
3. Heparins:
   - Unfractionated heparin (UFH)
   - Low molecular weight heparin (LMWH)
4. Direct thrombin inhibitors:
   - Bivalirudin
   - Hirudin
5. Vitamin K antagonists

   Note: Warfarin and other vitamin K antagonists were considered but not recommended routinely following PCI.

MAJOR OUTCOMES CONSIDERED

Clinical safety and effectiveness of treatments, as defined by:

- Relative risk of complications
- Mortality
- Rates of early ischemic complications following percutaneous coronary intervention (PCI), such as cardiac death, myocardial infarction (MI), the need for coronary bypass surgery (CABG), repeat angioplasty, target lesion revascularization, angiographic thrombosis
- Rates of adverse effects from treatment, such as bleeding

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Process of Searching for Evidence

Defining the clinical question provided the framework for formulating eligibility criteria that guided the search for relevant evidence. Prior to searching for the evidence, methodological experts and librarians reviewed each question to ensure that the librarians could derive a comprehensive search strategy.

In specifying eligibility criteria, authors not only identified patients, interventions, and outcomes, but also methodological criteria. For most therapeutic studies, authors restricted eligibility to randomized controlled trials (RCTs).

For many questions, RCTs did not provide sufficient data, and article authors also included observational studies. This was also true when randomized trials were not the most appropriate design to use for addressing the research question. In particular, randomized trials are not necessarily the best design to understand risk groups (e.g., the baseline or expected risk of a given event for certain subpopulations). Because there are no interventions examined in questions about prognosis, one replaces interventions by the exposure, which is time.

Identifying the Evidence

To identify the relevant evidence, a team of librarians at the University at Buffalo conducted comprehensive literature searches. For each question the authors provided, the librarians developed sensitive (but not specific) search strategies, including all languages, and conducted separate searches for systematic reviews, RCTs, and, if applicable, observational studies. The librarians searched the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effectiveness and Cochrane Register of Controlled Trial, the ACP Journal Club, MEDLINE, and Embase for studies published between 1966 and June 2002 in any language. To filter MEDLINE and Embase search results for RCT evidence, the librarians used the search strategy developed by the Cochrane Collaboration (full strategy available in Appendix online at:
http://www.chestjournal.org/content/vol126/3_suppl_1).

For observational studies, they restricted their searches to human studies. Searches were not further restricted in terms of methodology. While increasing the probability of identifying all published studies, this sensitive approach resulted in large number of citations for many of the defined clinical questions. Therefore, trained research assistants screened the citation list developed from the search and removed any apparently irrelevant citations. These irrelevant citations included press news, editorials, narrative reviews, single case reports, animal studies (any nonhuman studies), and letters to the editor. Authors included data from abstracts of recent meetings if reporting was transparent and all necessary data for the formulation of a recommendation were available. The guideline developers did not explicitly use Internet sources to search for research data.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The rating scheme framework captures the trade-off between benefits and risks (1 or 2) (and the methodological quality of the underlying evidence (A, B, C+, or C). See "Rating Scheme for the Strength of the Recommendations."

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Observational Trials
Meta-Analysis of Randomized Controlled Trials
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Summarizing Evidence

The electronic searches also included searching for systematic reviews. If authors were satisfied with a recent high-quality systematic review, evidence from that review provided a foundation for the relevant recommendation.

Pooled analyses from high-quality systematic reviews formed, wherever possible, the evidence base of the recommendations. Pooling offers the advantage of obtaining more precise estimates of treatment effects and allows for a greater generalizability of results. However, pooling also bears the risk of spurious generalization. In general, the summary estimates of interest were the different types of outcomes conveying benefit and downsides (i.e., risk, burden, and cost).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The strength of any recommendation depends on the following two factors: the trade-off between the benefits and the risks, burdens, and costs; and the strength of the methodology that leads to the treatment effect. The guideline developers grade the trade-off between benefits and risks in the two categories: 1, in which the trade-off is clear enough that most patients, despite differences in values, would make the same choice; and 2, in which the trade-off is less clear, and individual patients´ values will likely lead to different choices.

When randomized trials provide precise estimates suggesting large treatment effects, and the risks and costs of therapy are small, treatment for average patients with compatible values and preferences can be confidently recommended.

If the balance between benefits and risks is in doubt, methodologically rigorous studies providing **Grade A** evidence and recommendations may still be weak

(**Grade 2**). Uncertainty may come from less precise estimates of benefit, harm, or costs, or from small effect sizes.

There is an independent impact of validity and consistency, and the balance of positive and negative impacts of treatment on the strength of recommendations. In situations in which there is doubt about the value of the trade-off, any recommendation will be weaker, moving from **Grade 1** to **Grade 2**.

Grade 1 recommendations can only be made when there is a relatively clear picture of both the benefits and the risks, burdens, and costs, and when the balance between the two clearly favors recommending or not recommending the intervention for the typical patient with compatible values and preferences. A number of factors can reduce the strength of a recommendation, moving it from **Grade 1** to **Grade 2**. Uncertainty about a recommendation to treat may be introduced if the following conditions apply: (1) the target event that is trying to be prevented is less important (confident recommendations are more likely to be made to prevent death or stroke than asymptomatic deep vein thrombosis); (2) the magnitude of risk reduction in the overall group is small; (3) the probability of the target event is low in a particular subgroup of patients; (4) the estimate of the treatment effect is imprecise, as reflected in a wide confidence interval (CI) around the effect; (5) there is substantial potential harm associated with therapy; or (6) there is an expectation for a wide divergence in values even among average or typical patients. Higher costs would also lead to weaker recommendations to treat.

The more balanced the trade-off between benefits and risks, the greater the influence of individual patient values in decision making. Virtually all patients, if they understand the benefits and risks, will take aspirin after experiencing a myocardial infarction (MI) or will comply with prophylaxis to reduce the risk of thromboembolism after undergoing hip replacement. Thus, one way of thinking about a **Grade 1** recommendation is that variability in patient values is unlikely to influence treatment choice in average or typical patients.

When the trade-off between benefits and risks is less clear, individual patient values may influence treatment decisions even among patients with average or typical preferences.

Grade 2 recommendations are those in which variation in patient values or individual physician values will often mandate different treatment choices, even among average or typical patients. An alternative, but similar, interpretation is that a **Grade 2** recommendation suggests that clinicians conduct detailed conversations with patients to ensure that their ultimate recommendation is consistent with the patient's values.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grade of Recommendation	Clarity of Risk/Benefit	Methodological Strength of Supporting Evidence	Implications

Grade of Recommendation	Clarity of Risk/Benefit	Methodological Strength of Supporting Evidence	Implications
1A	Clear	Randomized controlled trials (RCTs) without important limitations	Strong recommendation; can apply to most patients in most circumstances without reservation
1C+	Clear	No RCTs, but strong RCT results can be unequivocally extrapolated, or overwhelming evidence from observational studies	Strong recommendation; can apply to most patients in most circumstances
1B	Clear	RCTs with important limitations (inconsistent results, methodological flaws*)	Strong recommendation; likely to apply to most patients
1C	Clear	Observational studies	Intermediate-strength recommendation; may change when stronger evidence is available
2A	Unclear	RCTs without important limitations	Intermediate-strength recommendation; best action may differ depending on circumstances or patients' or societal values
2C+	Unclear	No RCTs, but strong RCT results can be unequivocally	Weak recommendation; best action may differ depending on

Grade of Recommendation	Clarity of Risk/Benefit	Methodological Strength of Supporting Evidence	Implications
		extrapolated, or overwhelming evidence from observational studies	circumstances or patients' or societal values
2B	Unclear	RCTs with important limitations (inconsistent results, methodological flaws*)	Weak recommendation; alternative approaches likely to be better for some patients under some circumstances
2C	Unclear	Observational studies	Very weak recommendation; other alternatives may be equally reasonable

These situations include RCTs with both lack of blinding and subjective outcomes, where the risk of bias in measurement of outcomes is high, or RCTs with large loss to follow-up.

COST ANALYSIS

While conference participants agreed that recommendations should reflect economic considerations, incorporating costs is fraught with difficult challenges. For most recommendations, formal economic analyses are unavailable. Even when analyses are available, they may be methodologically weak or biased. Furthermore, costs differ radically across jurisdictions, and even sometimes across hospitals within jurisdictions.

Because of these challenges, the guideline developers consider economic factors only when the costs of one therapeutic option over another are substantially different within major jurisdictions in which clinicians make use of these recommendations. As a result, in jurisdictions in which resource constraints are severe, alternative allocations may serve the health of the public far better than some of the interventions that are designate as **Grade 1A**. This will likely be true for all less industrialized countries and, with the increasing promotion of expensive drugs with marginal benefits, may be increasingly true for wealthier nations. Furthermore, recommendations change (either in direction or with respect to grade) only when the guideline developers believe that costs are high in relation to benefits. Instances in which costs have influenced recommendations

are labeled in the "values and preferences" statements associated with the recommendation.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline authors formulated draft recommendations prior to the conference that served as the foundation for authors to work together and critique the recommendations. Drafts of all articles including draft recommendations were available for review during the conference. A representative of each article presented potentially controversial issues in their recommendations at plenary meetings. Article authors met to integrate feedback, to consider related recommendations in other articles, and to revise their own guidelines accordingly. Authors continued this process after the conference until they reached agreement within their groups and with other author groups who had provided critical feedback. Finally, the editors of this supplement harmonized the articles and resolved remaining disagreements through facilitated discussion.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The rating scheme is defined at the end of the "Major Recommendations" field.

Patients Undergoing Percutaneous Coronary Intervention (PCI): Oral Antiplatelet Therapy

Aspirin

1. For patients undergoing PCI, the guideline developers recommend pretreatment with aspirin, 75 to 325 mg (**Grade 1A**).
2. For long-term treatment after PCI, the guideline developers recommend aspirin, 75 to 162 mg/day (**Grade 1A**).
3. For long-term treatment after PCI in patients who receive antithrombotic agents such as clopidogrel or warfarin, the guideline developers recommend lower-dose aspirin, 75 to 100 mg/day (**Grade 1C+**).

Thienopyridine Derivatives

Ticlopidine versus Clopidogrel after Stent Placement

1. For patients who underwent stent placement, the guideline developers recommend the combination of aspirin and a thienopyridine derivative (ticlopidine or clopidogrel) over systemic anticoagulation therapy (**Grade 1A**).
2. The guideline developers recommend clopidogrel over ticlopidine (**Grade 1A**).

Pretreatment with Thienopyridines prior to PCI

1. The guideline developers recommend a loading dose of 300 mg of clopidogrel at least 6 hours prior to planned PCI (**Grade 1B**). If clopidogrel is started <6 hours prior to PCI, the guideline developers suggest a 600-mg loading dose of clopidogrel (**Grade 2C**).
2. If ticlopidine is administered, the guideline developers recommend a loading dose of 500 mg at least 6 hours before planned PCI (**Grade 2C**).

Aspirin Intolerant Patients

1. For PCI patients who cannot tolerate aspirin, the guideline developers recommend that the loading dose of clopidogrel (300 mg) or ticlopidine (500 mg) be administered at least 24 hours prior to the planned PCI (**Grade 2C**).

Duration of Thienopyridine Therapy after Stent Placement

1. After PCI, the guideline developers recommend, in addition to aspirin, clopidogrel (75 mg/day) for at least 9 to 12 months (**Grade 1A**).
2. If ticlopidine is used in place of clopidogrel after PCI, the guideline developers recommend ticlopidine for 2 weeks after placement of a bare metal stent in addition to aspirin (**Grade 1B**).
3. In patients with low atherosclerotic risk, such as those with isolated coronary lesions, the guideline developers recommend clopidogrel for at least 2 weeks after placement of a bare metal stent (**Grade 1A**), for 2 to 3 months after placement of a sirolimus-eluting stent (**Grade 1C+**), and 6 months after placement of a paclitaxel-eluting stent (**Grade 1C**).

Other Oral Antiplatelet Agents

1. For patients after stent placement, the guideline developers suggest ticlopidine (**Grade 1B**) or clopidogrel (**Grade 1C**) over cilostazol.
2. In aspirin-intolerant patients undergoing PCI, the guideline developers suggest clinicians **not** use dipyridamole as an alternative to a thienopyridine derivative (**Grade 2C**).

Patients Undergoing PCI: Glycoprotein (GP) IIb-IIIa Inhibitors

1. For all patients undergoing PCI, particularly those undergoing primary PCI, or those with refractory unstable angina (UA) or other high-risk features, the guideline developers recommend use of a GP IIb-IIIa antagonist (abciximab or eptifibatide) (**Grade 1A**).
2. In patients undergoing PCI for ST-segment elevation myocardial infarction (STEMI), the guideline developers recommend abciximab over eptifibatide (**Grade 1B**).

   Remark: Whenever possible, abciximab should be started prior to balloon inflation.

3. The guideline developers recommend administration of abciximab as a 0.25 mg/kg bolus followed by a 12-hour infusion at a rate of 10 micrograms/min

(**Grade 1A**) and eptifibatide as a double bolus (each 180 micrograms/kg administered 10 min apart), followed by an 18-hour infusion of 2.0 micrograms/kg/min (**Grade 1A**).

4. In patients undergoing PCI, the guideline developers recommend **against** the use of tirofiban as an alternative to abciximab (**Grade 1A**).
5. For patients with non-ST-segment elevation myocardial infarction (NSTEMI)/UA who are designated as moderate-to-high risk based on thrombolysis in myocardial infarction (TIMI) score, the guideline developers recommend that upstream use of GP IIb-IIIa antagonist (either eptifibatide or tirofiban) be started as soon as possible prior to PCI (**Grade 1A**).
6. In NSTEMI/UA patients who receive upstream treatment with tirofiban, the guideline developers recommend that PCI be deferred for at least 4 hours after initiating the tirofiban infusion (**Grade 2C**).
7. With planned PCI in NSTEMI/UA patients with an elevated troponin level, the guideline developers recommend that abciximab be started within 24 hours prior to the intervention (**Grade 1A**).

Underlying values and preferences: These recommendations for the use of GP IIb-IIIa inhibitors place a relatively high value on preventing cardiovascular events and a relatively low value on cost and bleeding complications.

Patients Undergoing PCI: Unfractionated Heparin (UFH)

1. In patients receiving a GP IIb-IIIa inhibitor, the guideline developers recommend a heparin bolus of 50 to 70 IU/kg to achieve a target activated clotting time (ACT) >200 seconds (**Grade 1C**).
2. In patients not receiving a GP IIb-IIIa inhibitor, the guideline developers recommend that heparin be administered in doses sufficient to produce an ACT of 250 to 350 seconds (**Grade 1C+**). The guideline developers suggest a weight-adjusted heparin bolus of 60 to 100 IU/kg (**Grade 2C**).
3. In patients after uncomplicated PCI, the guideline developers recommend **against** routine postprocedural infusion of heparin (**Grade 1A**).

Patients Undergoing PCI: Low Molecular Weight Heparin (LMWH)

1. In patients who have received LMWH prior to PCI, the guideline developers recommend that administration of additional anticoagulant therapy is dependent on the timing of the last dose of LMWH (**Grade 1C**). If the last dose of enoxaparin was administered <8 hours prior to PCI, the guideline developers suggest no additional anticoagulant therapy (**Grade 2C**). If the last dose of enoxaparin was administered between 8 hours and 12 hours before PCI, the guideline developers suggest a 0.3 mg/kg bolus of intravenous (IV) enoxaparin at the time of PCI (**Grade 2C**). If the last enoxaparin dose was administered >12 hours before PCI, the guideline developers suggest conventional anticoagulation therapy during PCI (**Grade 2C**).

Patients Undergoing PCI: Direct Thrombin Inhibitors

1. For patients undergoing PCI who are not treated with a GP IIb-IIIa antagonist, the guideline developers recommend bivalirudin (0.75 mg/kg

bolus followed by an infusion of 1.75 mg/kg/hour for the duration of PCI) over heparin during PCI (**Grade 1A**).

2. In PCI patients who are at low risk for complications, the guideline developers recommend bivalirudin as an alternative to heparin as an adjunct to GP IIb-IIIa antagonists (**Grade 1B**).

3. In PCI patients who are at high risk for bleeding, the guideline developers recommend bivalirudin over heparin as an adjunct to GP IIb-IIIa antagonists (**Grade 1B**).

Patients Undergoing PCI: Vitamin K Antagonists

1. In patients who undergo PCI with no other indication for systemic anticoagulation therapy, the guideline developers recommend **against** routine use of warfarin (or other vitamin K antagonists) after PCI (**Grade 1A**).

<u>**Definitions**</u>

Grade of Recommendation	Clarity of Risk/Benefit	Methodological Strength of Supporting Evidence	Implications
1A	Clear	Randomized controlled trials (RCTs) without important limitations	Strong recommendation; can apply to most patients in most circumstances without reservation
1C+	Clear	No RCTs, but strong RCT results can be unequivocally extrapolated, or overwhelming evidence from observational studies	Strong recommendation; can apply to most patients in most circumstances
1B	Clear	RCTs with important limitations (inconsistent results, methodological flaws*)	Strong recommendation; likely to apply to most patients
1C	Clear	Observational studies	Intermediate-strength

Grade of Recommendation	Clarity of Risk/Benefit	Methodological Strength of Supporting Evidence	Implications
			recommendation; may change when stronger evidence is available
2A	Unclear	RCTs without important limitations	Intermediate-strength recommendation; best action may differ depending on circumstances or patients' or societal values
2C+	Unclear	No RCTs, but strong RCT results can be unequivocally extrapolated, or overwhelming evidence from observational studies	Weak recommendation; best action may differ depending on circumstances or patients' or societal values
2B	Unclear	RCTs with important limitations (inconsistent results, methodological flaws*)	Weak recommendation; alternative approaches likely to be better for some patients under some circumstances
2C	Unclear	Observational studies	Very weak recommendation; other alternatives may be equally reasonable

*These situations include RCTs with both lack of blinding and subjective outcomes, where the risk of bias in measurement of outcomes is high, or RCTs with large loss to follow-up.

CLINICAL ALGORITHM(S)

None provided

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of antiplatelet agents (e.g., aspirin, clopidogrel, and glycoprotein [GP] IIb-IIIa inhibitors) and anticoagulants (e.g., intravenous [IV] heparin, low molecular weight heparin [LMWH], or bivalirudin) during percutaneous coronary intervention (PCI) is aimed at improving early (30-day) clinical outcome, and focuses on preventing complications at the site of intervention. In contrast, extended therapy with antiplatelet drugs may reduce the frequency of thrombotic complications at remote sites.

POTENTIAL HARMS

- The primary risk of antithrombotic therapy is bleeding. Several tables in the original guideline document summarize the rates of complications and side effects, including major and minor hemorrhage, obtained from various studies of antithrombotic therapy.
- Side effects are common with ticlopidine, and the drug can cause neutropenia and thrombocytopenia. Clopidogrel is safer than ticlopidine and easier to administer. Thus, clopidogrel does not cause neutropenia, thereby obviating the need for blood count monitoring. Furthermore, hemolytic uremic syndrome and thrombotic thrombocytopenic purpura are rare complications of clopidogrel.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Interpreting the Recommendations

Clinicians, third-party payers, institutional review committees, or the courts should not construe these guidelines in any way as absolute dictates. In general, anything other than a **Grade 1A** recommendation indicates that the article authors acknowledge that other interpretations of the evidence, and other clinical policies, may be reasonable and appropriate. Even **Grade 1A** recommendations will not apply to all circumstances and all patients. For instance, the guideline developers have been conservative in their considerations of cost and have seldom downgraded recommendations from **Grade 1** to **Grade 2** on the basis of expense. As a result, in jurisdictions in which resource constraints are severe, alternative allocations may serve the health of the public far better than some of

the interventions that are designated ad **Grade 1A**. This will likely be true for all less industrialized countries and, with the increasing promotion of expensive drugs with marginal benefits, may be increasingly true for wealthier nations.

Similarly, following **Grade 1A** recommendations will at times not serve the best interests of patients with atypical values or preferences or of those whose risks differ markedly from those of the usual patient. For instance, consider patients who find anticoagulant therapy extremely aversive, either because it interferes with their lifestyle (e.g., prevents participation in contact sports) or because of the need for monitoring. Clinicians may reasonably conclude that following some **Grade 1A** recommendations for anticoagulation therapy for either group of patients will be a mistake. The same may be true for patients with particular comorbidities (e.g., a recent gastrointestinal bleed or a balance disorder with repeated falls) or other special circumstances (e.g., very advanced age) that put them at unusual risk.

The guideline developers trust that these observations convey their acknowledgment that no recommendations or clinical practice guidelines can take into account the often compelling and unique features of individual clinical circumstances. No clinician, and no body charged with evaluating a clinician's actions, should attempt to apply these recommendations in a rote or blanket fashion.

Limitations of Guideline Development Methods

The limitations of these guidelines include the possibility that some authors followed this methodology more closely than others, although the development process was centralized and supervised by the editors. Second, it is possible that the guideline developers missed relevant studies despite the comprehensive searching process. Third, the guideline developers did not centralize the methodological evaluation of all studies to facilitate uniformity in the validity assessments of the research incorporated into these guidelines. Fourth, if high-quality meta-analyses were unavailable, the guideline developers did not statistically pool primary study results using meta-analysis. Finally, sparse data on patient preferences and values, resources, and other costs represent additional limitations that are inherent to most guideline development methods.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Guideline Implementation Strategies

A full review of implementation strategies for practice guidelines is provided in the companion document titled "Antithrombotic and Antithrombolytic Therapy: From Evidence to Application." The review suggests that there are few implementation strategies that are of unequivocal, consistent benefit, and that are clearly and consistently worth resource investment. The following is a summary of the recommendations (see "Major Recommendations" for a definition of the recommendation grades).

To encourage uptake of guidelines, the guideline developers recommend that appreciable resources be devoted to distribution of educational material (**Grade 2B**).

They also suggest that:

- Few resources be devoted to educational meetings (**Grade 2B**)
- Few resources be devoted to educational outreach visits (**Grade 2A**)
- Appreciable resources be devoted to computer reminders (**Grade 2A**)
- Appreciable resources be devoted to patient-mediated interventions to encourage uptake of the guidelines (**Grade 2B**)
- Few resources be devoted to audit and feedback (**Grade 2B**)

IMPLEMENTATION TOOLS

Patient Resources
Personal Digital Assistant (PDA) Downloads
Quick Reference Guides/Physician Guides
Resources
Slide Presentation
Tool Kits

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Popma JJ, Berger P, Ohman EM, Harrington RA, Grines C, Weitz JI. Antithrombotic therapy during percutaneous coronary intervention: the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. Chest 2004 Sep;126(3 Suppl):576S-99S. [143 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Jan (revised 2004 Sep)

GUIDELINE DEVELOPER(S)

American College of Chest Physicians - Medical Specialty Society

GUIDELINE DEVELOPER COMMENT

SOURCE(S) OF FUNDING

GUIDELINE COMMITTEE

American College of Chest Physicians Consensus Panel on Antithrombotic and Thrombolytic Therapy

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

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GUIDELINE STATUS

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GUIDELINE AVAILABILITY

Electronic copies: Available from the Chest - The Cardiopulmonary and Critical Care Journal.

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. Evidence-based guidelines. Northbrook, IL: ACCP, 2004 Sep.
- Methodology for guideline development for the Seventh American College of Chest Physicians Conference on Antithrombotic and Thrombolytic Therapy. Northbrook, IL: ACCP, 2004 Sep.
- Applying the grades of recommendation for antithrombotic and thrombolytic therapy: The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. Northbrook, IL: ACCP, 2004 Sep.
- Hemorrhagic complications of anticoagulant treatment: The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. Northbrook, IL: ACCP, 2004 Sep.
- Antithrombotic and thrombolytic therapy: from evidence to application: The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. Northbrook, IL: ACCP, 2004 Sep.
- Platelet-active drugs: the relationships among dose, effectiveness, and side effects: The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. Northbrook, IL: ACCP, 2004 Sep.

Electronic copies: Available from the Chest - The Cardiopulmonary and Critical Care Journal Web site.

Print copies: Available from the American College of Chest Physicians (ACCP), Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

The following is also available:

- Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy: Evidence-based guidelines; quick reference guide. Northbrook, IL: ACCP, 2004 Sep. Personal Digital Assistant (PDA) download available at ACCP Web site.

Additional implementation tools are also available:

- Clinical resource: antithrombotic and thrombolytic therapy. Northbrook, IL. ACCP, 2004. Ordering information: Available from the ACCP Web site.

PATIENT RESOURCES

The following is available:

- A patient's guide to antithrombotic and thrombolytic therapy. In: Clinical resource: antithrombotic and thrombolytic therapy. Northbrook (IL): American College of Chest Physicians (ACCP). 2004.

Ordering information is available from the ACCP Web site.

advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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